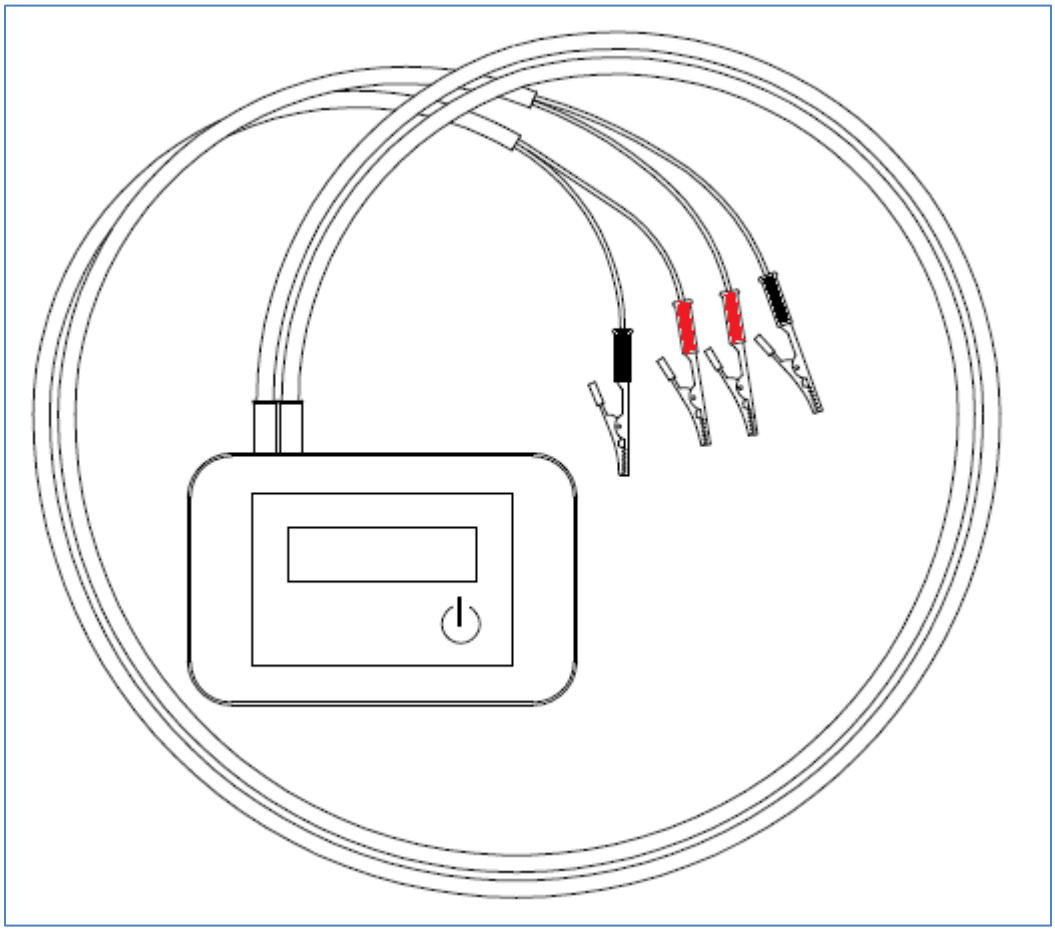
EFRESH® ANALYZER USER MANUAL



USER MANUAL REVISED 6 January 2014

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Chapter One: Basic Overview

Statement of Intended Utilization of the EFresh Analyzer™

The EFresh Analyzer™ is a specialized bioimpedance analysis device intended only for the measurement of Impedance, Resistance, Reactance and Phase Angle in foods. The test results provide an objective index of the cellular health of foods that equate to freshness, the characteristics of palatability (flavorfulness, tenderness, juiciness), as well as to determine of the food, particularly fish, has been previously frozen but sold or offered as 'fresh'. The EFresh System includes the instrument, a portion sized fixed-distance hand-heal electrode array and ongoing training, support and communication.

Precautions

1. Follow all instructions, directions and suggestions; contact the Company with any questions prior to using.
2. Treat the device with care and gentleness to extend its useful life, do not impact the device.
3. Do not immerse the device in liquids or get it wet in any way.
    a. Thoroughly cleanse the fixed distance electrode array after each use to avoid cross-contamination
4. Use the device in a comfortable and controlled environment and not in extremes of temperature or humidity.
5. Do not bend, kink or otherwise compromise the subject cables.
6. Do not use the device if any component is broken.
7. Do not open the device case or modify any part of the device.
8. If you are not going to use the device for more than a month remove the batteries and replace them when you use the device again, use fresh batteries as needed.
9. For service on the device contact the Company.

Symbols, Abbreviations and Definitions

1. "Z" = impedance; the total opposition force of conduction measured in ohms.
2. "R" = resistance; one of the two vectors of phase sensitive impedance measured in ohms.
3. "X" = reactance; one of the two vectors of phase sensitive impedance measured in ohms.
4. "PA" = phase angle, the arc-tangent of X and R expressed in degrees

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Chapter Two: Specifications

Warranty

The device is warranted for a period of one-year (twelve-months) to be without defects in materials and/or workmanship from the delivery date specified in the invoice and the warranty covers parts and labor only.

Please note that you must register the warranty with the Company for it to be in effect and that registration must be made and the information received by the Company within thirty days of your receipt of the device.

The Company is responsible for repair or replacement at its discretion to cure any defects under the warranty.

A return merchandise authorization (RMA) must be issued by the company prior to returning the device to the company or receipt of a replacement device.

Contact the Company to agree on the delivery method and the documentation to be provided together with the instrument.

The Company declares that the content of this manual is accurate; however, we reserve the right to modify, change or revise this document. If the user thinks that there are some errors, they are recommended to contact the Company.

The Company does not provide any express or implicit guarantee for the misuse of the device.

The right of the user to ask for compensation due to fault or negligence of the Company is limited to the amount paid by the Customer for the purchase of the instrument.

This warranty does not cover and is void if the failure of your instrument is caused by defects, malfunctions, breaks or damages resulting from the non-observance of the use and maintenance instructions for the instrument.

The Company is not responsible for and the warranty will be revoked and cancelled if the user makes changes, improper use or misuse of the instrument.

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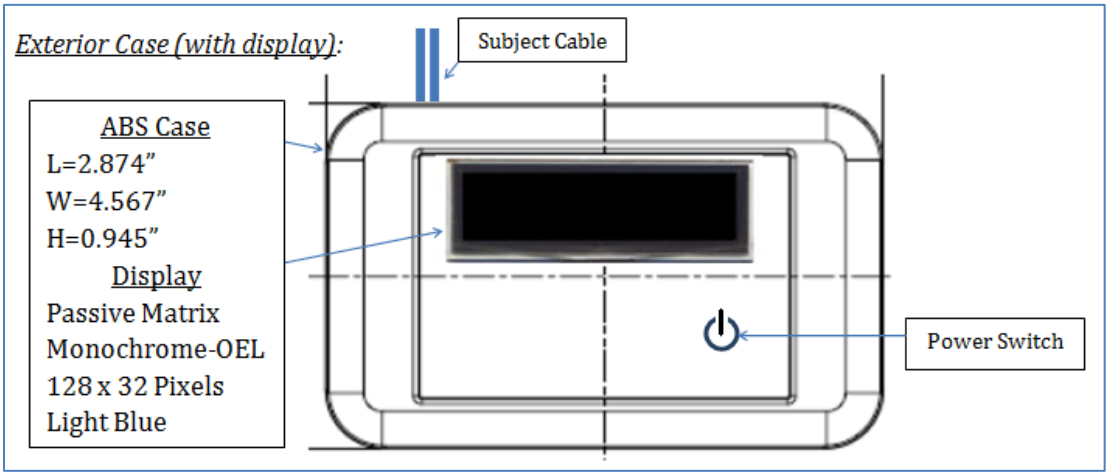
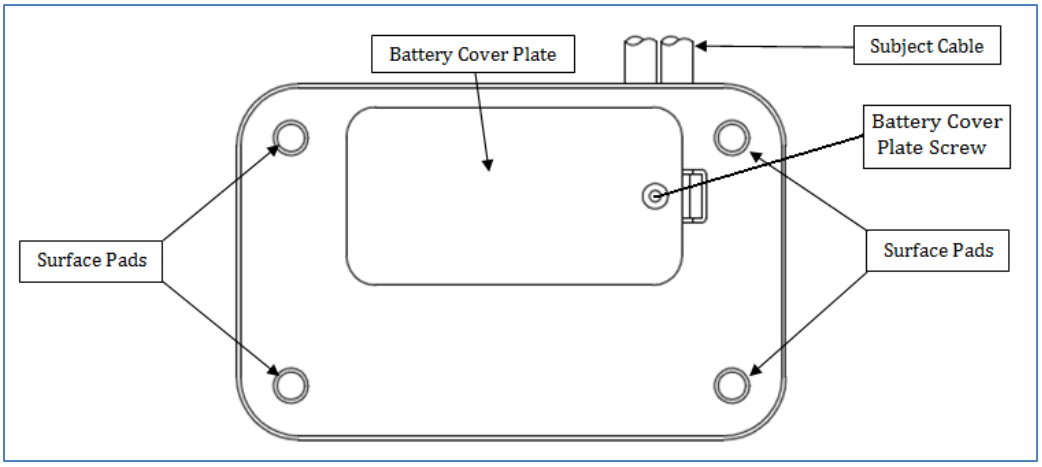
Description

The EFresh® Analyzer is a generic bioimpedance analysis device intended only for the measurement of Impedance, Resistance, Reactance and Phase Angle in in foods.

Exterior Front



Exterior Back



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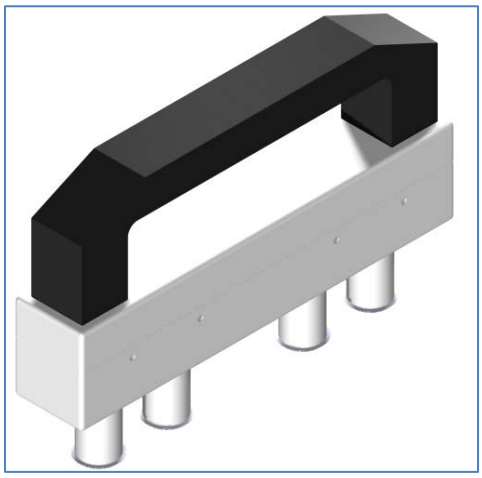
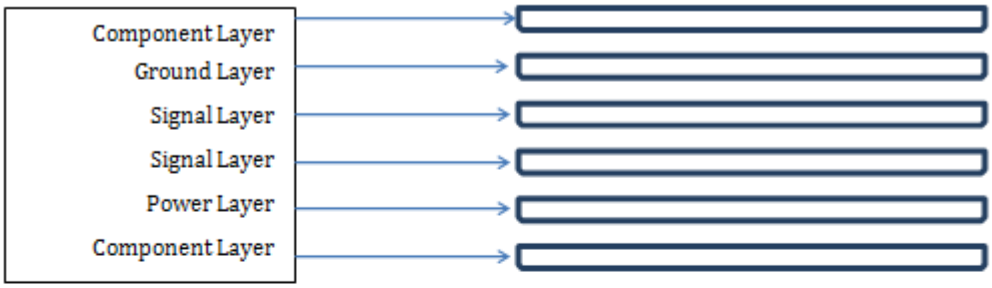
Fixed Distance Electrode Array



Internal Electronic Systems

Six-Layer Custom Circuit Board:



Key Components:

- Impedance Analyzer Circuit
- Digital Signal Processor
- A/D and D/A
- Subject Cable
- Display
- Batteries (x2AA)

Features:

- Digital Signal Processor
- Eco-Power Management System (Disposable AA batteries)
  - Subject connected: automatic power off in 45 seconds
  - Subject disconnected: automatic power off in 8 seconds
- Measures Impedance, Resistance, Reactance and Phase Angle

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Technical Operating Specifications

Power Supply

The device is powered by two disposable "AA" batteries housed on the back accessed via a removable plastic cover. Carefully remove the screw from the cover and replace the screw when done changing the batteries. Batteries should be removed from the device if it is not to be used for more than thirty days. A "LOW-BATTERY" signal is displayed when the batteries require replacement. Battery life with multiple tests and daily utilization is about three months.

Maintenance and Repair

The device has no parts subject to user maintenance and repair. All maintenance and repair must be performed by the Company. Contact the Company for maintenance and repair.

Subject Cables

The subject cables are permanently affixed to the device and should not be removed, twisted, kinked or otherwise mistreated. The color coded clip-tips on each cable can be removed for cleaning as necessary. We recommend using a disposable alcohol pad to cleanse them after each use.

Fixed Distance Electrode Array

The fixed distance electrode array is made to make measurements on average portions. The subject cable is attached to the array with the two black subject cable ends at the beginning and end, as they introduce the electrical signal, and the two red subject cable ends inside the black ones as they make the measurement. The array should be thoroughly cleansed after each test between samples to prevent cross-contamination.

Cleaning the Device

We recommend that the device be wiped down after each use with a damp cloth. Do not use any solvents or cleaning agents on the device.

Storage and Transport

Store and transport the device in its original box container with the batteries removed in a dry, safe and room temperature environment of 15° to 35° (C), humidity 30% to 60% and atmospheric pressure 86-106 kPa.

Use

The device can be used as frequently as necessary with testing multiple times daily for months prior to battery power loss. Battery power loss is alerted on the display as noted above. You should not use the device in a wet environment or allow the device to be exposed to moisture. If the device is immersed contact the Company to arrange for repair at your expense. It is not possible to hurt the food with the device.

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Calibration and Check

The device is self-validating and performs the validation routine internally each time it is energized.

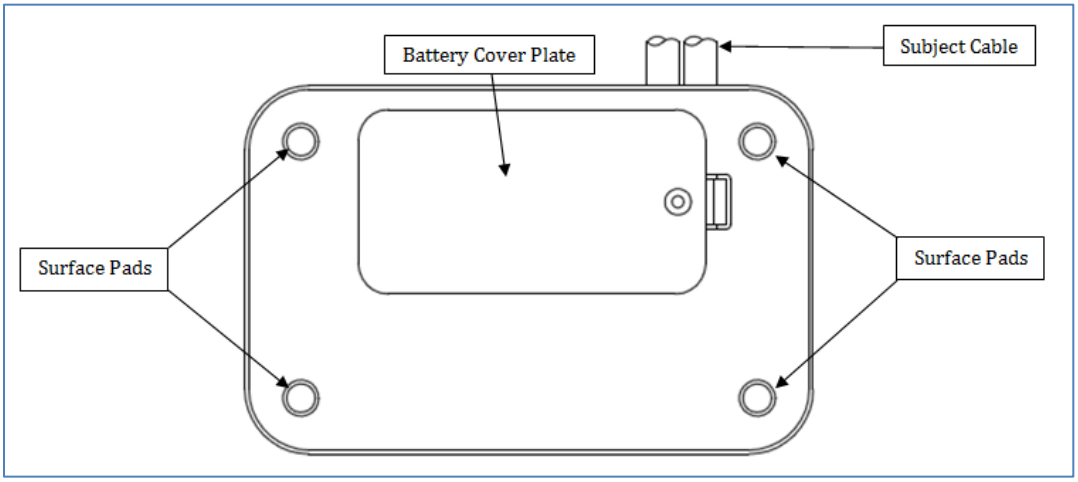
Technical Specifications

1. Device type: Fixed frequency, phase-sensitive, bioimpedance analyzer
2. Device name: EFresh® Analyzer
3. Measures: Impedance, resistance, reactance and phase angle
4. Output Signal: Nominal: 425 µA ±25 µA at 50 KHz crystal controlled, Sinusoidal wave form
    a. Range: 0 to 10,000 ohms, resistive or capacitive
5. Measured Value Accuracy: impedance-resistance-reactance: Nominal: ± 1.0 Ω, Range: 0 to 1000 Ω, Resolution: 1 Ω
    a. Phase Angle: Resolution: 0.1 degree, Range: 0 to 360°
6. Power Supply: two disposable "AA" batteries
7. Protection Class: Internal source medical device
8. Dimensions: L=2.874", W=4.567", H=0.945"
    a. Weight: 14.5 ounces (with batteries)
9. Operating Conditions: 45° to 85° (F) and between 30% and 80% humidity

Chapter Three: Operation and Testing

To Begin

1. Once the device is removed from its shipping container;
    a. Remove the protective film from the display
    b. Place the two "AA" batteries in the device



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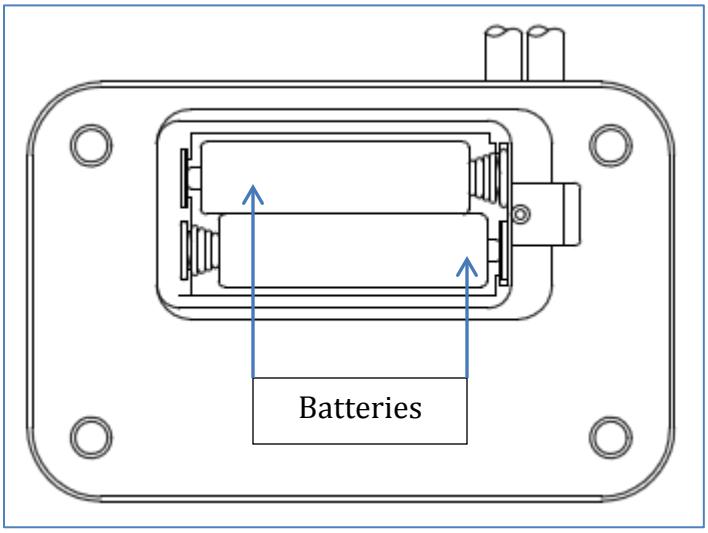
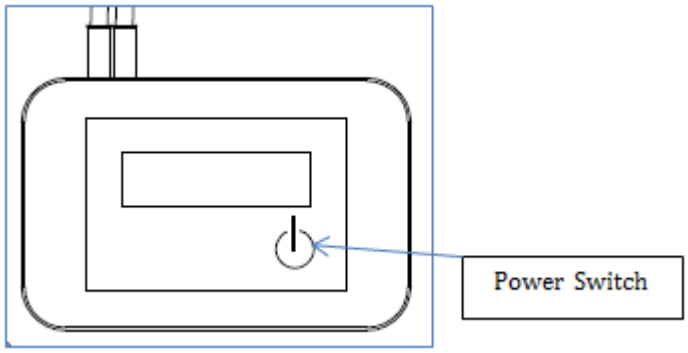
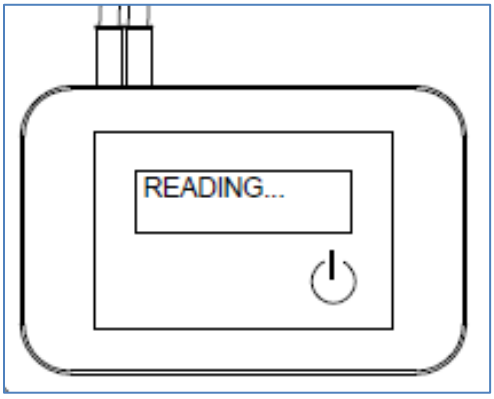


Device Power Management

1. Press the on-off switch on the right side of the front panel under the display area.



2. The device will turn itself off.
3. Once the device is connected to a subject it will self-validate and begin the reading.



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Performing a Test

Bioimpedance testing is the measurement of electrical values from a safe and highly controlled electrical circuit introduced into the test subject by two electrodes that introduce and set-up the circuit and two electrodes that make the measurement.

THE EFRESH® ANALYZER IS FOR USE ON FOODS ONLY!

It is important for the examiner to perform each test carefully and in the same manner so the data is accurate and subsequent measurements can be compared. The examiner should practice testing until they feel comfortable with the testing procedure. The examiner should be able to complete a test and a second test one after the other with the results of both tests being within one-percent of each other; this demonstrates proficiency of the examiner.

The person acting as the examiner should familiarize themselves with the testing materials, procedures and method and explain them to the subject being tested and answer any questions prior to testing. If you have any questions about the testing procedure you can call the Company to have them answered.

The subject should be prepared by;

- Placed on a non-conductive surface
- Portion size subjects should be patted dry and not in pooled fluids

First gather the device, electrode array, test subject material and writing materials to the testing area. The testing surface should be non-conductive surface (not a metal surface) and large enough for the test subject to lie flat upon.

The electrode array is placed directly on the subject.

Next, the examiner should energize the device and then turn towards the test subject to ensure that the array is in contact with the subject material, flat and not moving. Then the examiner should record the measured values from the device.

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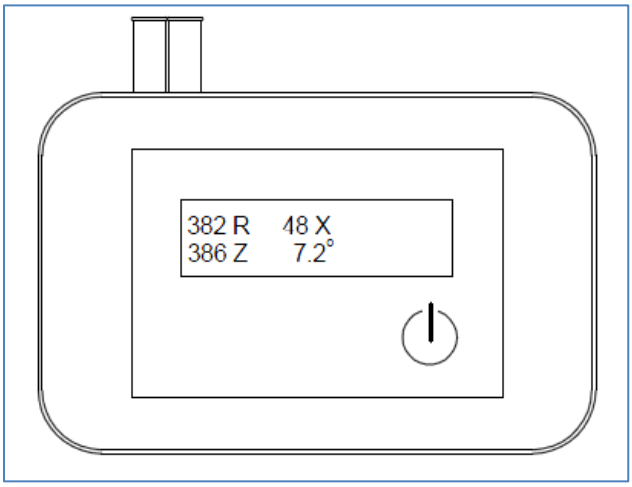

Once the results are written down the examiner should remove the electrode array from the subject.

Non-portion size subjects require custom electrode arrays to fit their size. Generally we use penetrating electrodes of a size proportional to the size of the subject. For instance; in small portions four-straight pins or needles can be used, larger portions may require finishing nails or brass rods in primal cuts or whole-body studies. Large cuts, whole-body and large specimens can be tested hanging but always on a non-conductive surface should lay out flat.

REMEMBER WHEN ATTACHING THE ELECTRODE CLIPS THAT THE BLACK CLIPS INTRODUCE THE ELECTRICAL SIGNAL AND SET-UP THE CIRCUIT SO THEY ARE PLACED AT THE TOP/BOTTOM, BEGINNING/END OF THE SUBJECT BEING TESTED, THE RED CLIPS WITHIN THE BLACK.

The test procedure is the same however when you remove the fixed electrode array, place the color coded clips on the ends of each cable to attach to your penetrating electrodes. The penetrating electrodes should be placed inline, with the signal introduction and detection electrodes apart the full distance of what the cable-ends allow and then the other cable is placed at the opposite end of the subject. The specific area of interest should be between the detection electrodes. Once the electrodes are placed, connect the cables, energize the device and record the readings.

If you have any questions regarding the testing procedure please feel free to contact the Company; 989-724-5631, info@ipgdx.com.

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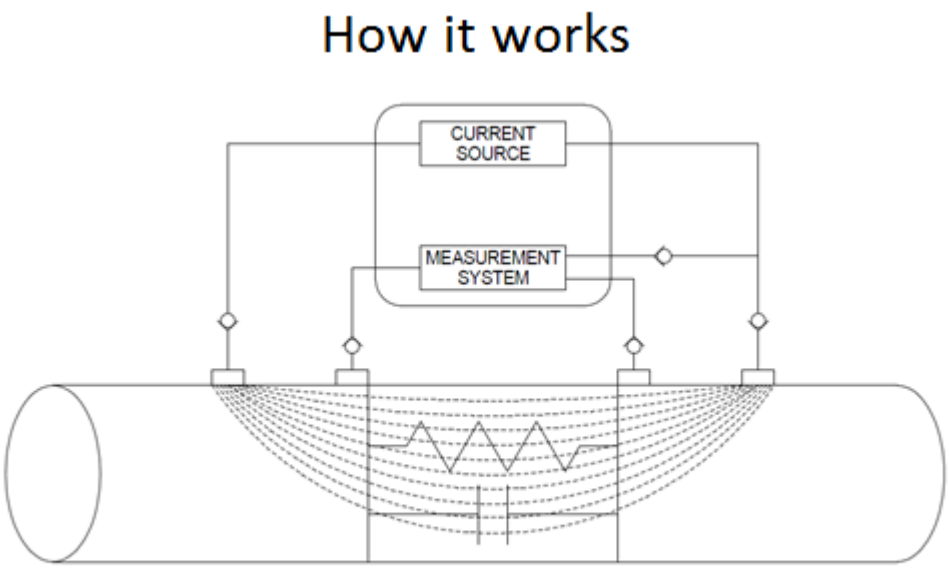

Interpreting Your Results

Foodstuff result analysis is simple and straight-forward as the measured value relate directly to fluid volume/resistance, cell volume/reactance and cell membrane integrity/phase angle. The Resistance value is higher with less fluid and lower with more fluid corresponding to adipose as well as adipose (fat) has significantly less fluid and therefore more Resistance than lean tissue which has much more fluid and therefore less Resistance. The reactance value is proportional to cell mass and a surrogate for freshness. The phase angle value is highest upon harvest and reduces over time based upon preservation methods. Both reactance and phase angle go to zero if the foodstuff has been previously frozen as freezing results in the breakdown of cell membranes.

The “Vitality Index®” is the scored phase angle value.

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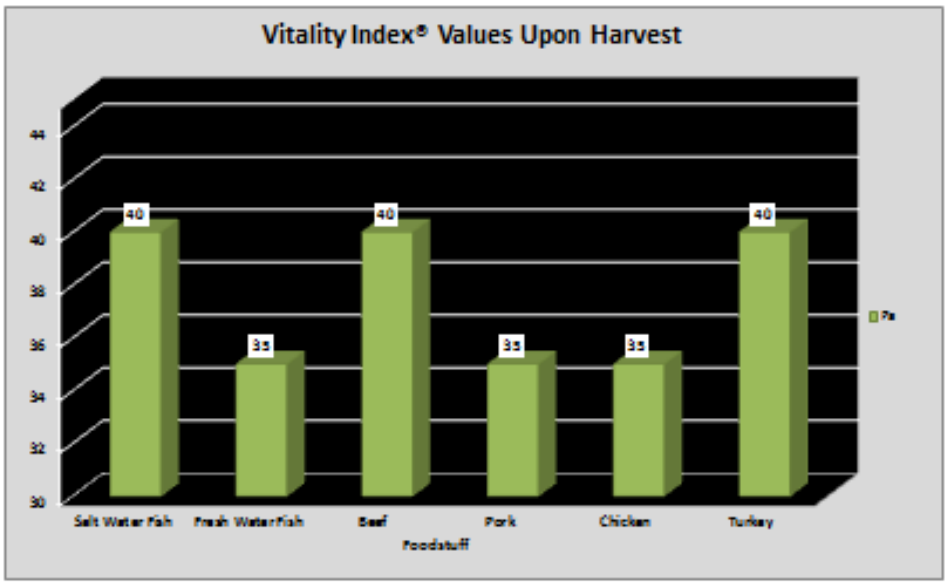
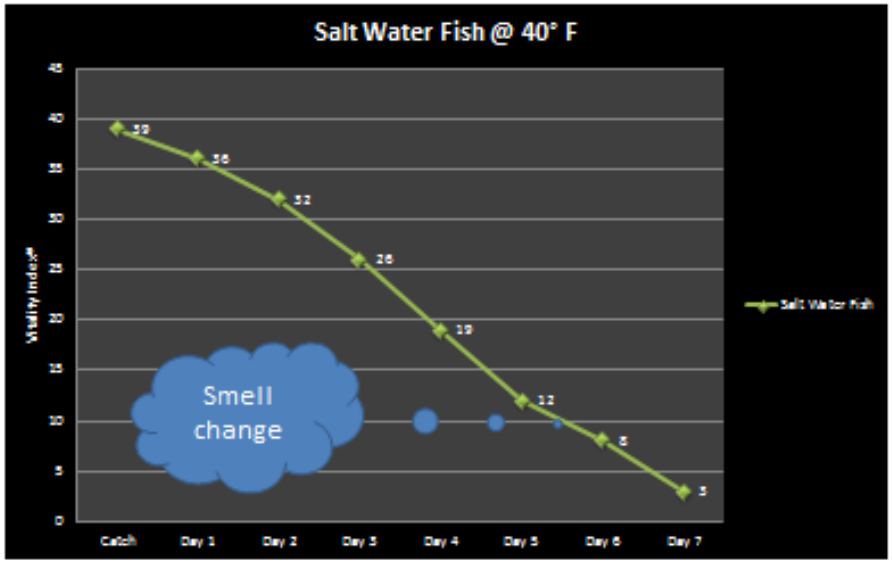
Measured Values



Change over time



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Some foods are best immediately upon harvest such as fish, fowl and vegetables, while others are best once they age or mature as their cells breakdown as in beef, pork and fruits. For instance when sorting beef or pork steaks the specimens with the highest resistance and lowest phase angle are the most flavorful and tender as the higher resistance indicates more fat and flavor and the lower phase angle that the cell membranes have broken down and are tenderer.

In fish for instance higher phase angles and best flavor are found upon harvest such as a freshwater fish which begins at 35°, salt water at 40°. So if your specimen has a phase angle above 25° the fish is fine as a stand-alone entrée while fish below 25° but above 15° may be better sauced, spiced or in a secondary role.

Over time you will grow accustomed to the specific values and changes seen in the specimens you use or study.

Most importantly, please feel free to call and discuss any questions.

Chapter Four: Service

Step One

Always communicate with the Company first regarding any problems with the device. There is no service that you can perform on the device.

Step Two

If necessary the Company may ask you to return the device for repair or replacement, if so you will be issued a Return Merchandise Authorization (RMA) number, package the device professionally and send it to the Company.

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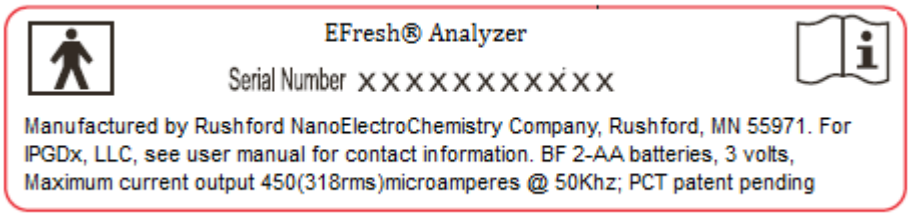
Device photo

Device Labeling


EFresh® Analyzer
Serial Number XXXXXXXXXXX
Manufactured by Rushford NanoElectroChemistry Company, Rushford, MN 55971. For IPGDx, LLC, see user manual for contact information. BF 2-AA batteries, 3 volts, Maximum current output 450(318rms)microamperes @ 50Khz; PCT patent pending

This symbol designates the device as International Electro-Technical Commission category designation “BF” denoting energy transfer to the subject with a non-permanent contact under IEC60601 standards.

This symbol indicates referring the reader to the device user manual (this document).

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Company contact information

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